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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,376	09/25/2003	Janina Baranowska-Kortylewicz	0685-UNMC.63184	1854

110 7590 07/05/2005

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PHILADELPHIA, PA 19103-2307

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,376	<b>Applicant(s)</b> BARANOWSKA-KORTYLEWICZ ET AL.	
	<b>Examiner</b> Howard V. Owens	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 5-9 is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/11/04</u> . | 6) <input type="checkbox"/> Other: _____  |

*18*

### **DETAILED ACTION**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

#### **Claim Objections**

Claim 18 appears to contain the misspelled term "imagining". Appropriate correction is required for this and any other spelling or grammatical errors not noted herein.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Quivy et al., U.S. 5,096,694.

Claims 1-4 are drawn to a radiolabeled conjugate, wherein the nucleobase is a radiolabelled thymidine.

Claims 10-13 are drawn to a method of treating cancer (ovarian, prostate, breast) using the conjugate of claim 1.

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Quivy anticipates the instant claims when "R"= an alkyl substituted phospho group as it teaches a radiolabelled substituted thymidine wherein the radionuclide is an Auger electron emitting radioisotope (see col. 2, lines 16-64). Quivy also teaches that these conjugates are used to treat a number of cancers with high concentrations of specific receptors for estrogens, progestagens, or androgens, which provide utility for the treatment of breast, uterus, ovary and prostate cancers with the conjugate compounds (see col. 4, lines 18-33).

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-4 and 10-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Quivy et al., U.S. 5,096,694.

Claims 1-4 are drawn to a radiolabeled conjugate, wherein the nucleobase is a radiolabelled thymidine.

Claims 10-13 are drawn to a method of treating cancer (ovarian, prostate, breast) using the conjugate of claim 1.

Claims 14-17 are drawn to routes of administration and the timetable of administration.

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Claim 18 is drawn to the use of a scintograph to image the tumor.

Quivy teaches the conjugate when "R"= an alkyl substituted phospho group as it teaches a radiolabelled substituted thymidine wherein the radionuclide is an Auger electron emitting radioisotope (see col. 2, lines 16-64). Quivy also teaches that these conjugates are used to treat a number of cancers with high concentrations of specific receptors for estrogens, progestagens, or androgens, which provide utility for the treatment of breast, uterus, ovary and prostate cancers with the conjugate compounds (see col. 4, lines 18-33).

Quivy does not specifically state that a scintograph is used to image the tumor; however, Quivy does cite that the radionuclide ( $I^{125}$  or  $I^{123}$ ) is useful for radioimaging, wherein one of the principal instruments used for radioimaging is a scintigraph.

Quivy does not specifically cite the route of administration nor the timetable of administration; however, a *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done. Given routine experimentation common to practice of an invention in any art, one of skill in the art would have been provided with a clear motivation and a reasonable expectation of success in the use of art accepted routes of administration for the treatment of cancer. Moreover, one of skill in the art routinely adjusts the dosage and timetable of administration based on the grade of cancer as well as the patient's tolerance and metabolism.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer the compound of the invention intravenously, intraperitoneally, intratumor within a period of days or years.

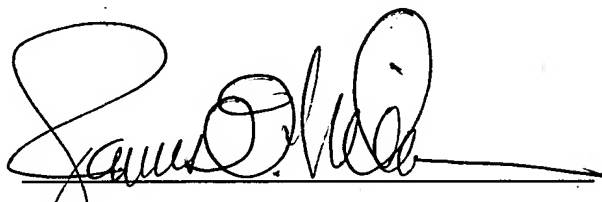
A person of ordinary skill in the art would have been motivated to administer the compound of the invention intravenously, intraperitoneally, intratumor within a period of days or years as these routes of administration are well known in the art and the nature of cancer treatment requires an adjustment to this administration over a daily or yearly period.

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Allowable Subject Matter

Claims 5-9 drawn to the ester linkage of the hormone(s) and the radionucleotide appear to contain subject matter allowable over the prior art of record.

Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.